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December 22, 2004

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APPLICATION NUMBER: 60/622,392

FILING DATE: *October 27, 2004*

RELATED PCT APPLICATION NUMBER: *PCT/US04/39400*

Certified by



Jon W Dudas

Acting Under Secretary of Commerce
for Intellectual Property
and Acting Director of the U.S.
Patent and Trademark Office



102704

14280 U.S. PTO

PTO/SB/16 (09-04)

Approved for use through 07/31/2006. OMB 0651-0032

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. US 068780295 US

102704
60/622392
U.S. PTO

102704

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Jeremy W.	Snow	North Salt Lake, Utah
Additional inventors are being named on the <u>1</u> separately numbered sheets attached hereto		
TITLE OF THE INVENTION (500 characters max):		
SAFETY SHIELD FOR MEDICAL NEEDLES		
Direct all correspondence to: CORRESPONDENCE ADDRESS		
<input checked="" type="checkbox"/> The address corresponding to Customer Number: <u>26,152</u>		
OR		
<input type="checkbox"/> Firm or Individual Name		
Address		
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ENCLOSED APPLICATION PARTS (check all that apply)		
<input checked="" type="checkbox"/> Specification Number of Pages <u>8</u>		
<input type="checkbox"/> CD(s), Number of CDs _____		
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets <u>16</u>		
<input type="checkbox"/> Other (specify) _____		
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76		
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT		
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.		
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees.		
FILING FEE Amount (\$) <u>160.00</u>		
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<input checked="" type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: _____		
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<input checked="" type="checkbox"/> The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government. No.		
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SIGNATURE Paul S. Evans

Date 10/25/04

TYPED or PRINTED NAME Paul S. Evans

REGISTRATION NO. 36,130

TELEPHONE 801-298-3360

(if appropriate)

Docket Number: SHP026.4.1.2

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PROVISIONAL APPLICATION COVER SHEET
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First Named Inventor	Jeremy W. SNOW	Docket Number SHP026.4.1.2
INVENTOR(S)/APPLICANT(S)		
Given Name (first and middle (if any))	Family or Surname	Residence (City and either State or Foreign Country)
F. Mark Donald D.	Ferguson Solomon	Salt Lake City, Utah North Salt Lake, Utah

Number 2 of 2

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**FEE TRANSMITTAL
for FY 2005**

Effective 10/01/2004. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 160.00

Complete if Known

Application Number	
Filing Date	27 October 2004
First Named Inventor	Jeremy W. SNOW
Examiner Name	
Art Unit	
Attorney Docket No.	SHP026.4.1.2

METHOD OF PAYMENT (check all that apply)☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:Deposit
Account
Number
Deposit
Account
Name

19-3542

Specialized Health Produc

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity Fee Code	Small Entity Fee Code	Fee Description	Fee Paid
1001 790	2001 395	Utility filing fee	
1002 350	2002 175	Design filing fee	
1003 550	2003 275	Plant filing fee	
1004 790	2004 395	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	160.00
SUBTOTAL (1)			(\$ 160.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims		-20** =		X		=	
Independent Claims		-3** =		X		=	
Multiple Dependent						=	

Large Entity Fee Code	Small Entity Fee Code	Fee Description	Fee Paid
1202 18	2202 9	Claims in excess of 20	
1201 88	2201 44	Independent claims in excess of 3	
1203 300	2203 150	Multiple dependent claim, if not paid	
1204 88	2204 44	** Reissue independent claims over original patent	
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent	
SUBTOTAL (2)			(\$)

**or number previously paid, if greater. For Reissues, see above

FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051 130		2051 65		Surcharge - late filing fee or oath	
1052 50		2052 25		Surcharge - late provisional filing fee or cover sheet	
1053 130		1053 130		Non-English specification	
1812 2,520		1812 2,520		For filing a request for ex parte reexamination	
1804 920*		1804 920*		Requesting publication of SIR prior to Examiner action	
1805 1,840*		1805 1,840*		Requesting publication of SIR after Examiner action	
1251 110		2251 55		Extension for reply within first month	
1252 430		2252 215		Extension for reply within second month	
1253 980		2253 490		Extension for reply within third month	
1254 1,530		2254 765		Extension for reply within fourth month	
1255 2,080		2255 1,040		Extension for reply within fifth month	
1401 340		2401 170		Notice of Appeal	
1402 340		2402 170		Filing a brief in support of an appeal	
1403 300		2403 150		Request for oral hearing	
1451 1,510		1451 1,510		Petition to institute a public use proceeding	
1452 110		2452 55		Petition to revive - unavoidable	
1453 1,370		2453 685		Petition to revive - unintentional	
1501 1,370		2501 685		Utility issue fee (or reissue)	
1502 490		2502 245		Design issue fee	
1503 660		2503 330		Plant issue fee	
1460 130		1460 130		Petitions to the Commissioner	
1807 50		1807 50		Processing fee under 37 CFR 1.17(q)	
1806 180		1806 180		Submission of Information Disclosure Stmt	
8021 40		8021 40		Recording each patent assignment per property (times number of properties)	
1809 790		2809 395		Filing a submission after final rejection (37 CFR 1.129(a))	
1810 790		2810 395		For each additional invention to be examined (37 CFR 1.129(b))	
1801 790		2801 395		Request for Continued Examination (RCE)	
1802 900		1802 900		Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)

SUBMITTED BY

(Complete (if applicable))

Name (Print/Type)	Paul S. Evans	Registration No. (Attorney/Agent)	36,130	Telephone	801-298-3360
Signature		Date	10/25/04		

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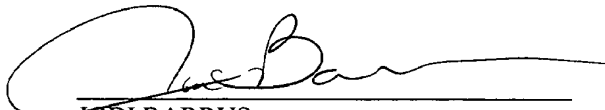
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Express Mail No. EV 068780295US

PROVISIONAL PATENT APPLICATION
Docket No: SHP026.4.1.2

CERTIFICATE OF MAILING BY EXPRESS MAIL

I hereby certify that the enclosed Provisional Patent Application consisting of 8 pages of specification, 16 sheets of drawings, and Check No. 011477 For \$160.00 in the matter of the Application of Specialized Health Products, Inc. for SAFETY SHIELD FOR NEEDLES; Declaration and Power of Attorney; Assignment and form PTO-1595; is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated below in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


JODI BARRUS

EV068780295US
EXPRESS MAIL LABEL NUMBER

October 27, 2004
DATE OF DEPOSIT

SAFETY SHIELD FOR MEDICAL NEEDLES

5

CROSS-REFERENCE TO RELATED APPLICATIONS

This patent application is a continuation-in-part of U.S. Utility Patent Application Serial No. 10/739,868, filed in the U.S. Patent and Trademark Office on December 18, 2003 by Ferguson et al., which claims priority to U.S. Utility Patent Application Serial
10 No. 10/409,819, filed in the U.S. Patent and Trademark Office on April 8, 2003 by Ferguson et al., and U.S. Utility Application Serial No. 10/322,288, filed in the U.S. Patent and Trademark Office on December 17, 2002 by Ferguson et al., which claims priority to U.S. Provisional Patent application Serial No. 60/424,655, filed in the U.S. Patent and Trademark Office on November 7, 2002 by Bagley et al., and U.S. Utility
15 Patent Application Serial No. 10/202,201, filed in the U.S. Patent and Trademark Office on July 23, 2002 by Ferguson et al., which is a continuation-in-part of U.S. Utility Patent Application Serial No. 09/809,357, filed in the U.S. Patent and Trademark Office on March 15, 2001 by Ferguson et al., the entire contents of each of these disclosures being hereby incorporated by reference herein.

20 **BACKGROUND**1. **Technical Field**

The present disclosure generally relates to safety shields for medical needles, and more particularly, to resettable safety shields that protect a needle point of a medical needle.

25 2. **Description of the Related Art**

Problems associated with inadvertent needle sticks are well known in the art of blood sampling, percutaneous medication injection and other medical procedures involving use of medical needles. Significant attention has been focused on needle stick

problems due to the contemporary sensitivity of exposure to AIDS, Hepatitis and other serious blood-borne pathogen exposures.

Procedures for removing a needle from a patient commonly require a technician to use one hand to place pressure at the wound site where the needle is being withdrawn, while removing the needle device with the other hand. It is also common practice for an attending technician to give higher priority to care for the patient than is given to disposal of a needle. In the case of typical needle devices without safety shields, such priority either requires the convenience of an available sharps container within reach or another means for safe disposal without leaving the patient's side. Providing adequate care while following safety procedures is often compounded by the patient's physical condition and mental state, such as in burn units and psychiatric wards. Under such conditions, it is difficult to properly dispose of a used needle while caring for a patient.

The widespread knowledge and history associated with needle care and disposal problems have resulted in numerous devices for preventing accidental needle sticks. Problems of current safety devices include difficulty of use and high cost due to their complexity and number of parts.

Other known devices employ sheaths that are spring activated, telescoping, pivoting, etc. These devices, however, may disadvantageously misfire or be cumbersome to activate. Further drawbacks of current devices include high manufacturing cost due to complexity and the number of parts. Thus, these type prior art devices may not adequately and reliably shield medical needle apparatus to prevent hazardous exposure.

Consequently, there remains a need to provide a more satisfactory solution for needle safety devices by overcoming the disadvantages and drawbacks of the prior art. Therefore, it would be desirable to provide a more adequate and reliable medical needle shield apparatus that employs a safety shield slidably movable along a medical needle to prevent hazardous exposure to a needle tip. It would be advantageous to provide such a safety shield that is capable of being reset to safely allow re-use of certain needle apparatus. Such a needle shield apparatus should be easily and reliably movable to shield a needle tip of a needle cannula.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

The exemplary embodiments of the medical needle shield apparatus and methods of operation disclosed are discussed in terms of medical needles for infusion of intravenous fluids, medication infusion or fluid collection, guiding of other needles, e.g.,
5 biopsy, and more particularly, in terms of needle shield apparatus employed with a needle cannula that prevent hazardous exposure to the needle tip, including, for example, inadvertent needle sticks. It is envisioned that the present disclosure, however, finds application to a wide variety of cannula needles and devices for the infusion of preventive medications, medicaments, therapeutics, etc. to a subject, such as, for example, epidural
10 needles, spinal needles, biopsy needles, chiba needles, potts courmand needles, coaxial introducer needles, Y-sites, etc. It is also envisioned that the present disclosure may be employed for collection of body fluids and/or tissues, including those employed during procedures relating to soft tissue biopsy, bone biopsy, phlebotomy, digestive, intestinal, urinary, veterinary, etc. It is contemplated that the medical needle shield apparatus may
15 be utilized with other medical needle applications including, but not limited to, fluid infusion, fluid collection, catheters, catheter introducers, guidewire introducers, biopsy needle introducers, spinal and epidural, biopsy, aphaeresis, dialysis, blood donor, Veress needles, Huber needles, etc.

In the discussion that follows, the term “proximal” refers to a portion of a
20 structure that is closer to a clinician, and the term “distal” refers to a portion that is further from the clinician. As used herein, the term “subject” refers to a patient that receives infusions or has blood and/or fluid collected therefrom using the medical needle shield apparatus. According to the present disclosure, the term “clinician” refers to an individual administering an infusion, performing fluid or tissue collection, installing or
25 removing a needle cannula from a medical needle shield apparatus and may include support personnel.

The following discussion includes a description of the medical needle shield apparatus, followed by a description of the method of operating the medical needle shield apparatus in accordance with the present disclosure. Reference will now be made in

detail to the exemplary embodiments of the disclosure, which are illustrated in the accompanying figures.

Turning now to the figures, wherein like components are designated by like reference numerals throughout the several views. Referring initially to FIGURES 1-16,
5 there is illustrated a medical needle shield apparatus, constructed in accordance with the principals of the present disclosure.

In certain applications it may be desirable to reset a locked friction based single aperture plate safety device that protects a contaminated sharp, such as a medical needle, stylet, etc. In such a circumstance, it is important to maintain the safety of the sharp
10 while allowing the reuse of the sharp. It is also important that the resetting procedure is intuitive and does not cause any major changes to current physician technique. The following invention disclosure provides a solution to reset a locked friction based single aperture plate safety device that is intuitive and allows continued safety of a contaminated sharp.

15 One embodiment illustrates an obturator 61 having reset geometry 62 intended to interact with the reset element 63. The obturator 61 may have a handle 70. The handle 70 may have a cavity 65 to protect the needle 66 during resetting. The obturator 61 may have a funnel 64 to guide the obturator 61 through the safety device 69 to the inner diameter of the needle 66. The funnel 64 may use locating surfaces 67 on the housing to
20 facilitate guiding. The funnel 64 may be slidable along the obturator 61 such that the funnel 64 allows the obturator 61 to pass through the funnel 64. The funnel 64 may also exist as a separate piece. The obturator 61 may also have a blocking element 68. The blocking element 68 may be positioned such that it prohibits resetting. The blocking element 68 may be movable such that the absence of the blocking element 68 can allow
25 resetting geometry 62 to interact with the reset element 63. The means for moving the blocking element 68 includes, but is not limited to, levers, hinges, buttons, locks, snaps, detents, etc.

In this embodiment the obturator 61 is configured such that after the obturator 61 is through the needle 66 and expels a sample the blocking element 68 prohibits the
30 resetting geometry 62 from interacting with the reset element 63. The blocking member

68 is the moved to a position such that the resetting geometry 62 interacts with the reset element 63. The resetting geometry 62 interacts with the reset element 63 such that the binding from the locked friction based single aperture plate 60 is released. This allows for the safety device 69 to be replaced in a location ready for reuse. It is also envisioned
5 that the resetting geometry 62 may be placed in other locations on the obturator 61 including, but not limited to, the opposite end of the obturator 61.

Another embodiment shows a safety device 89 having a reset interface 87 that can be manually activated to interact with the reset element 83. The reset interface 87 can be directly connected to the reset element 83. The reset element 83 may consist as a part of,
10 but not limited to, the following: hub/handle, inner housing 84, outer housing 85, aperture plate 86, obturator 81. Alternatively, the reset element 83 may be a separate piece that interacts with any of the above pieces. The reset interface 87 may be connected to or interact with reset geometry 82 that is intended to interact with the reset element 83 for the purpose of unlocking binding from the locked friction based single aperture plate 80.
15 The reset interface 87 may contain, but is not limited to, springs, hinges, levers, buttons, switches, slides, etc. The reset interface 87 may include a pairing of interfaces. This may be desirable to ensure proper finger placement. The pairing of interfaces may be offset to ensure an intentional effort is given to reset the safety device.

This reset interface 87 may require an additional aperture plate 88 such that the
20 unlocking of binding from the original locked friction based single aperture plate 80 does not cause the accidental removal of the safety device 89 from the contaminated sharp. The additional aperture plate 88 can be configured such that the activation of the reset interface 87 positions binding surfaces 86 in the safety device 89 to facilitate binding when the safety device 89 is urged distally. This measure can prevent accidental safety
25 device 89 removal from a contaminated sharp while allowing resetting to take place.

Another embodiment illustrates the use of a funnel 92 to guide an obturator 93 to the inner diameter of a needle 96. The funnel 92 may be configured such that it allows for a locking or friction fit to the needle 96. The funnel 92 may also be configured such that it uses locating features 93 on the safety device 99 for guiding the obturator 91 to the
30 inner diameter of the needle 96. The locating features 93 on the safety device 99 may

also be configured such that a desirable fit is accomplished to maintain position. Such fit interfaces include, but are not limited to, snap fit, friction fit, detents, etc. The option to use the funnel 92 with or without the safety device 99 may be desirable so that clinicians may choose to use the funnel 92 with the safety device 99 protecting the contaminated sharp to guide an obturator 91 to the inner diameter of the needle 96. This also allows for conventional use without safety devices.

The invention of the present disclosure may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

WHAT IS CLAIMED IS:

1. A medical needle shield apparatus comprising:
a shield slidably movable along a medical needle from a proximal position where a distal end of the needle is exposed, to a distal position where the shield protects the distal end
5 of the needle, said shield comprising:
a binding member having an aperture through which the needle passes, said aperture having binding surfaces;
a retainer integral with the binding member and in communication with the needle for temporarily retaining the binding surfaces in a non-binding position relative to the needle;
10 and
a positioning member including a friction element configured to engage the medical needle and generate a drag force to cause orientation of the binding member for positioning the binding surfaces to secure the shield to the needle when a portion of the retainer in contact with the needle is advanced past the distal end of the needle and allows the retainer to release
15 from the needle and move out of an axial path defined by the needle.

ABSTRACT OF THE DISCLOSURE

A medical needle shield apparatus is provided that includes a needle hub having an outer needle cannula extending therefrom. An inner needle is disposed for slidable movement with the outer needle cannula. At least one shield is extensible from a retracted position to an extended position to enclose a distal end of the inner needle. The shield includes a binding member disposed within the shield and defines binding surfaces that form an aperture configured for slidable receipt of the inner needle.

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1/16

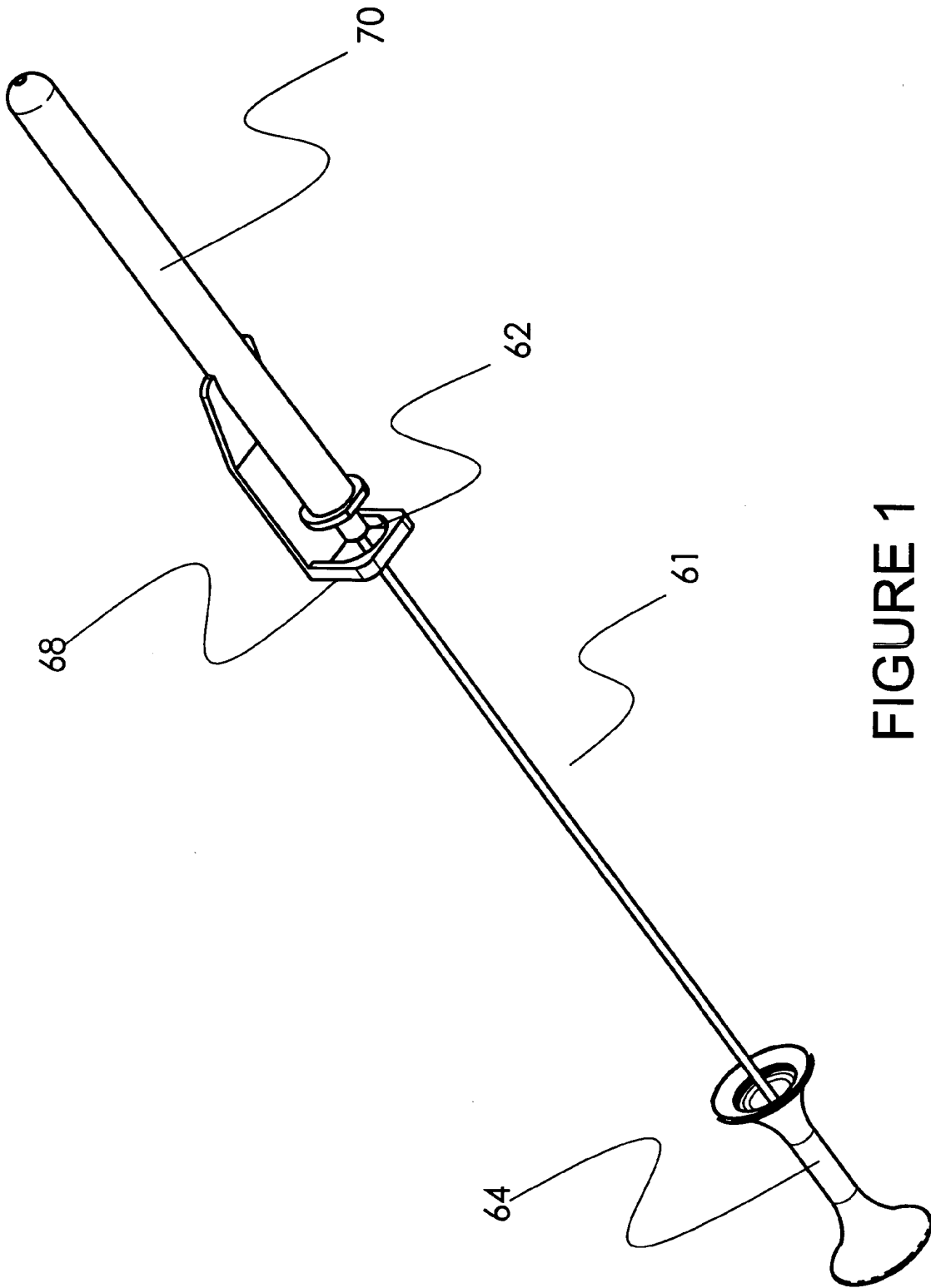


FIGURE 1

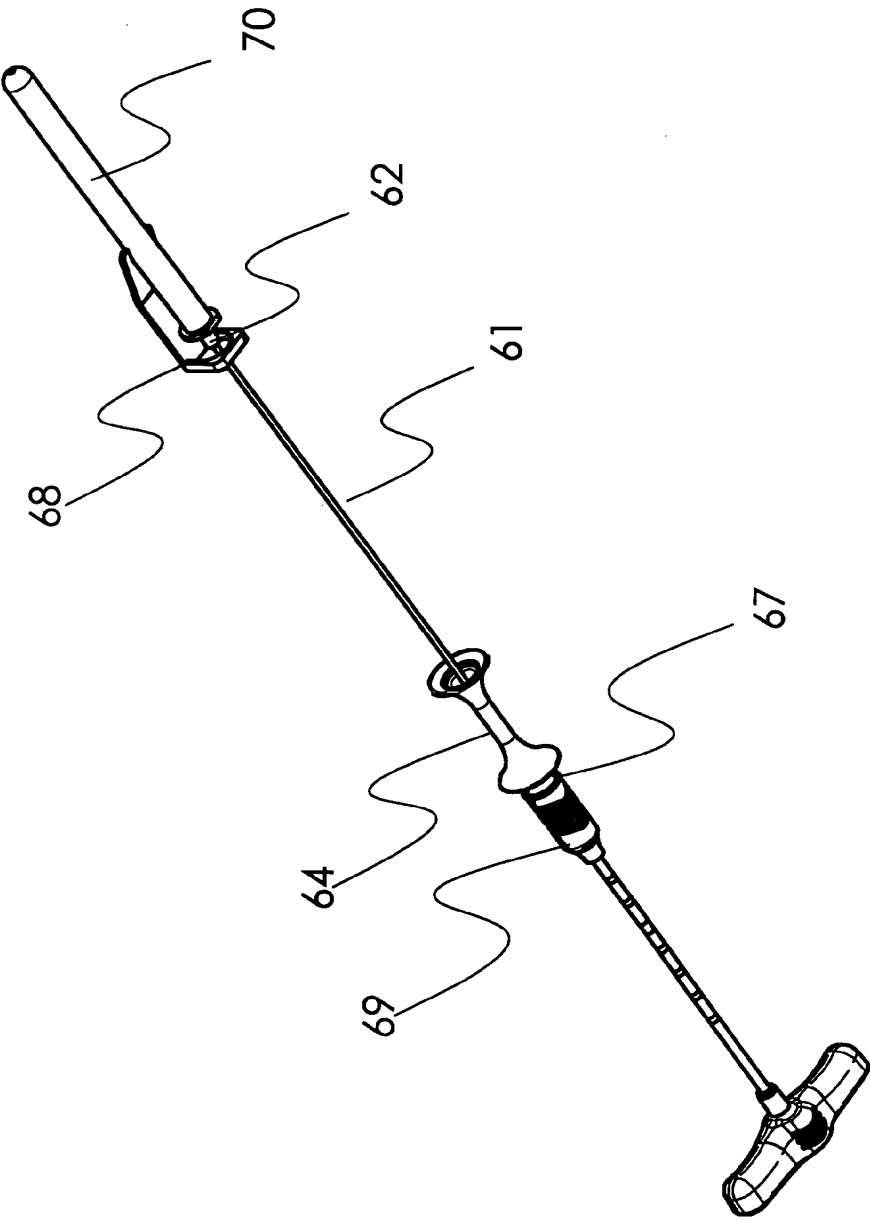


FIGURE 2

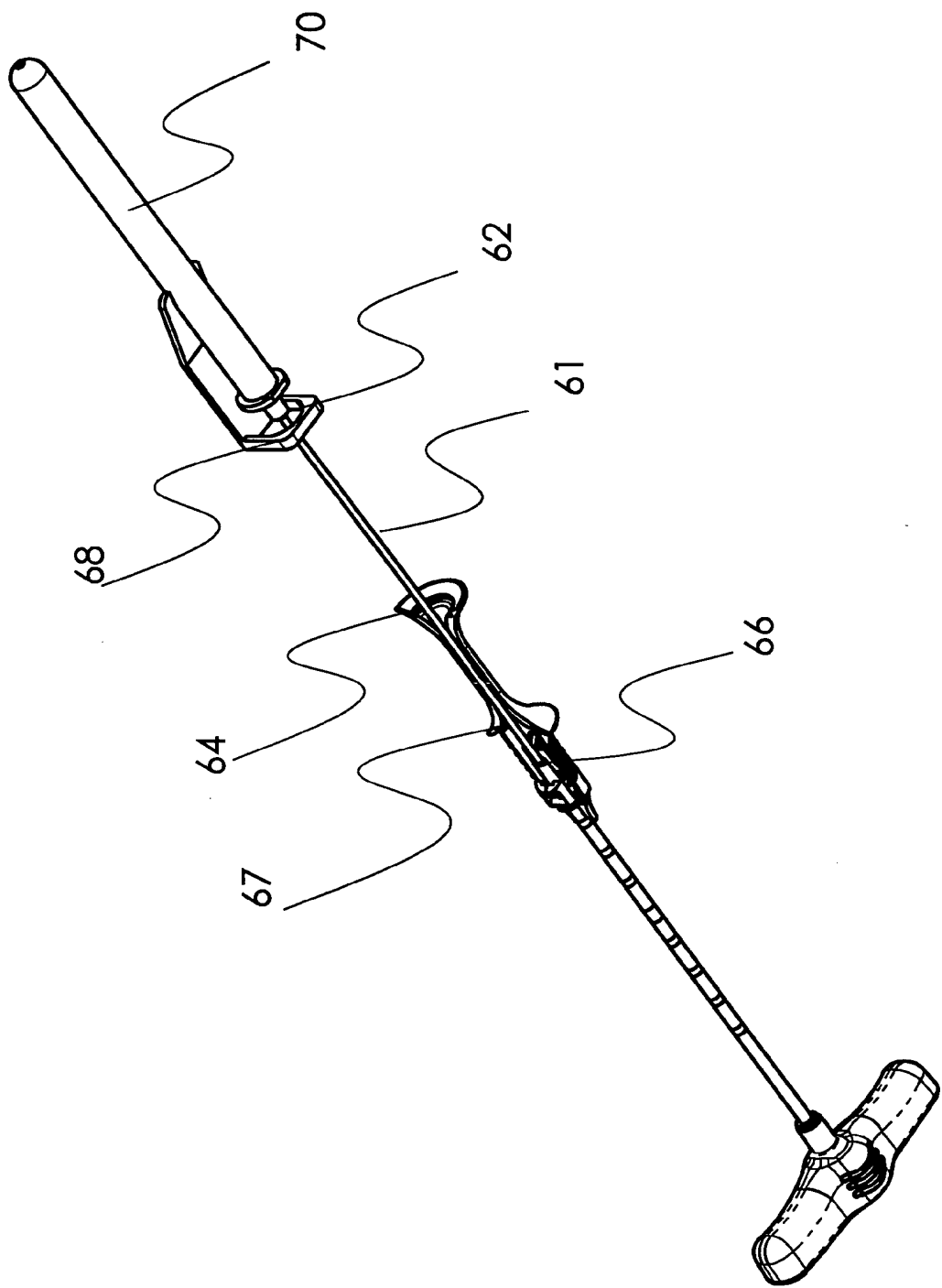


FIGURE 3

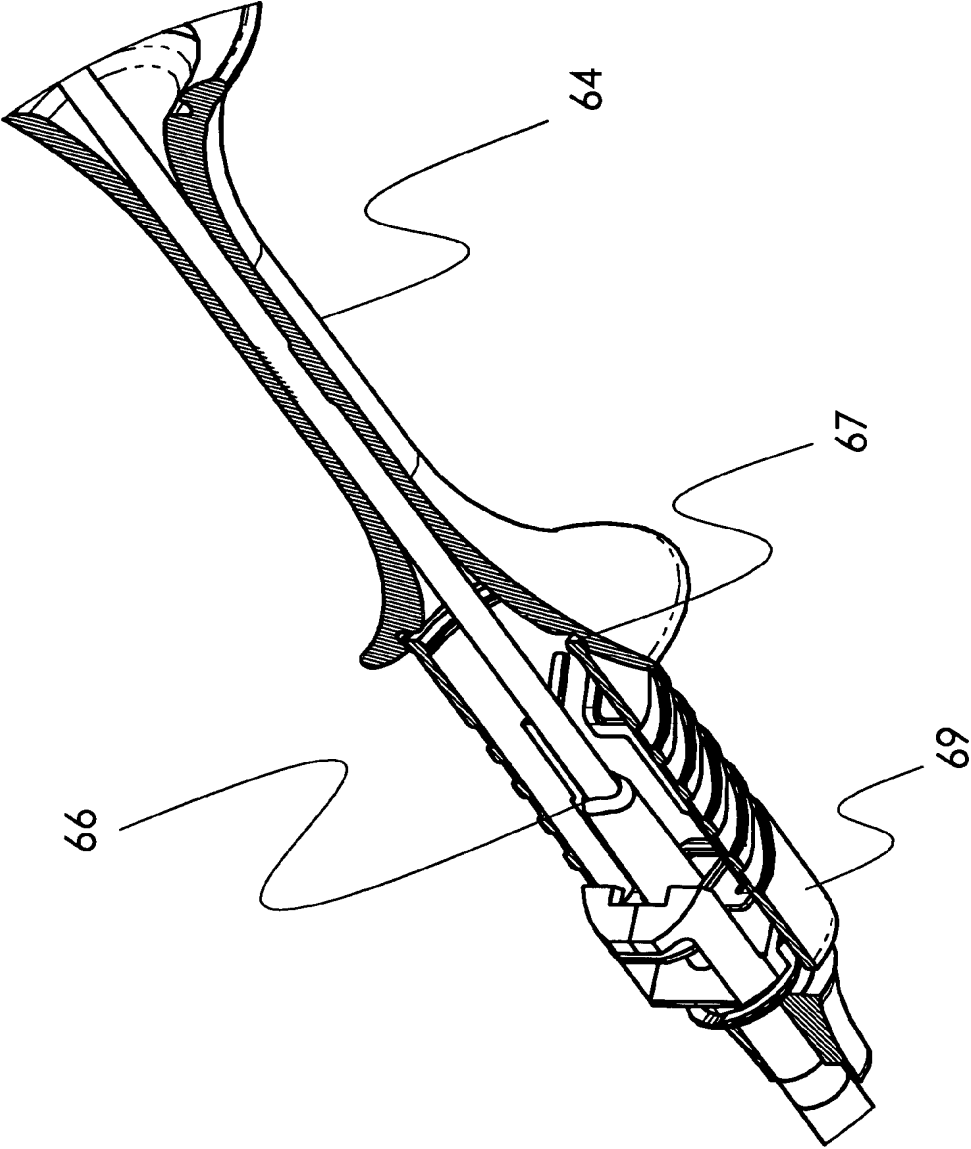


FIGURE 4

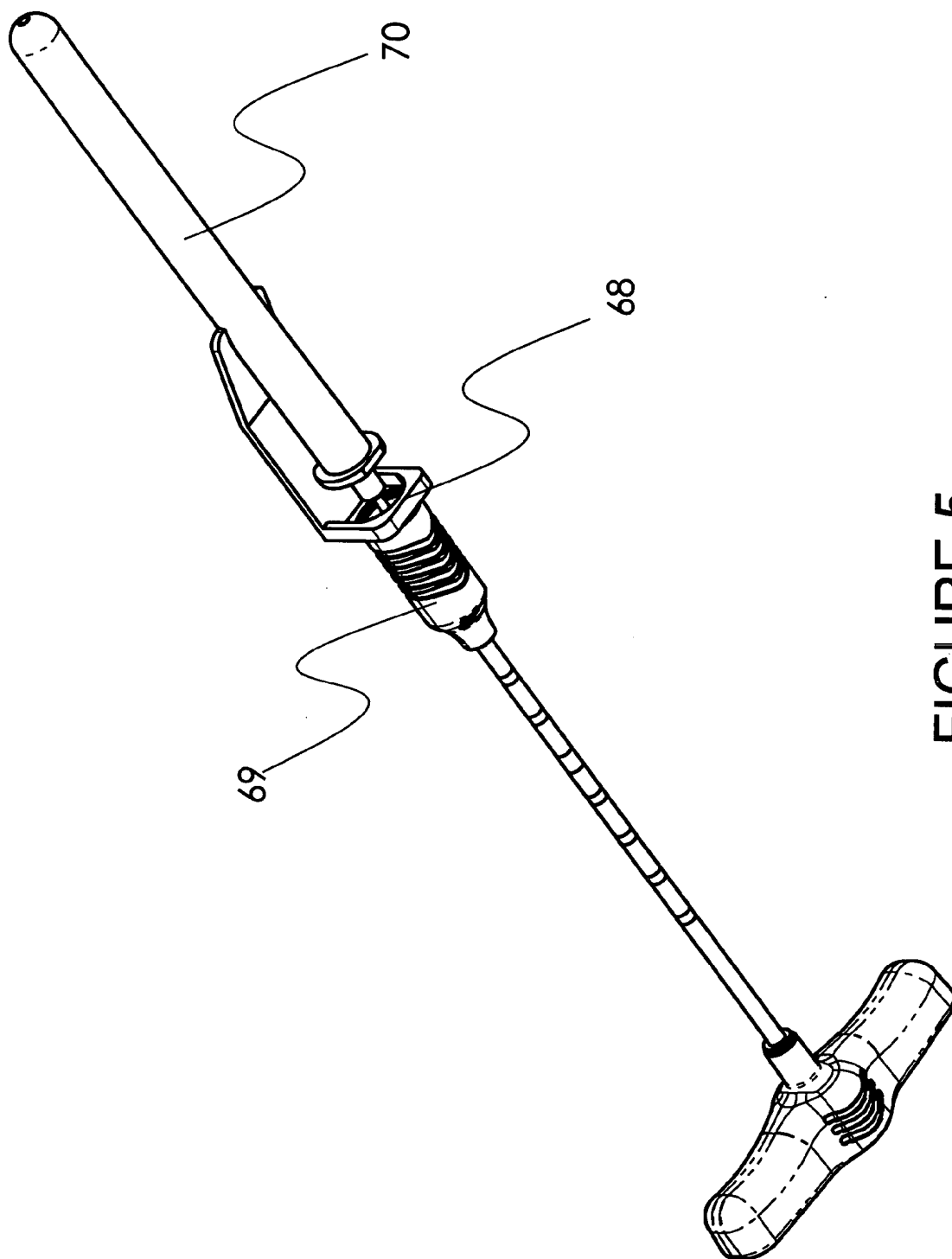


FIGURE 5

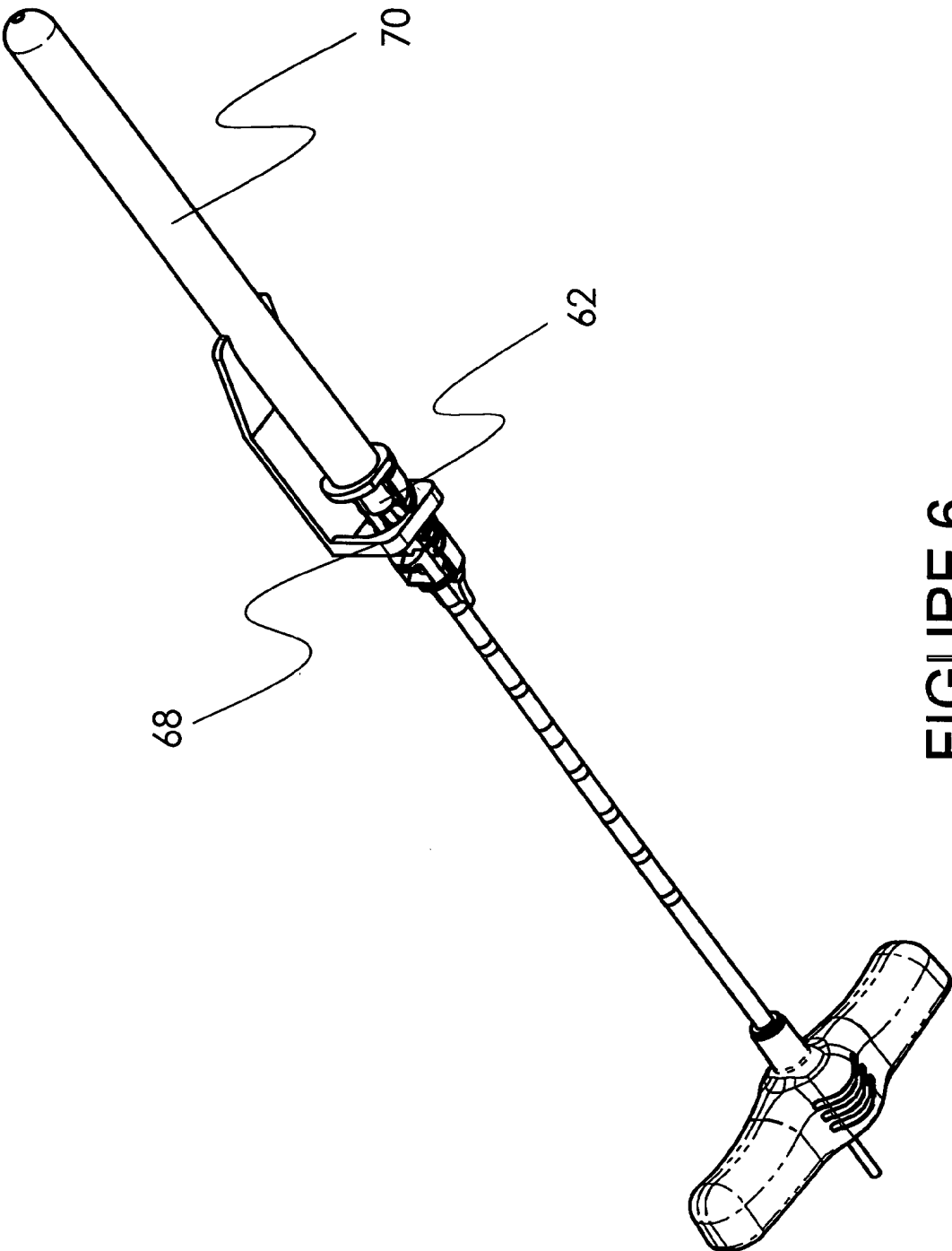


FIGURE 6

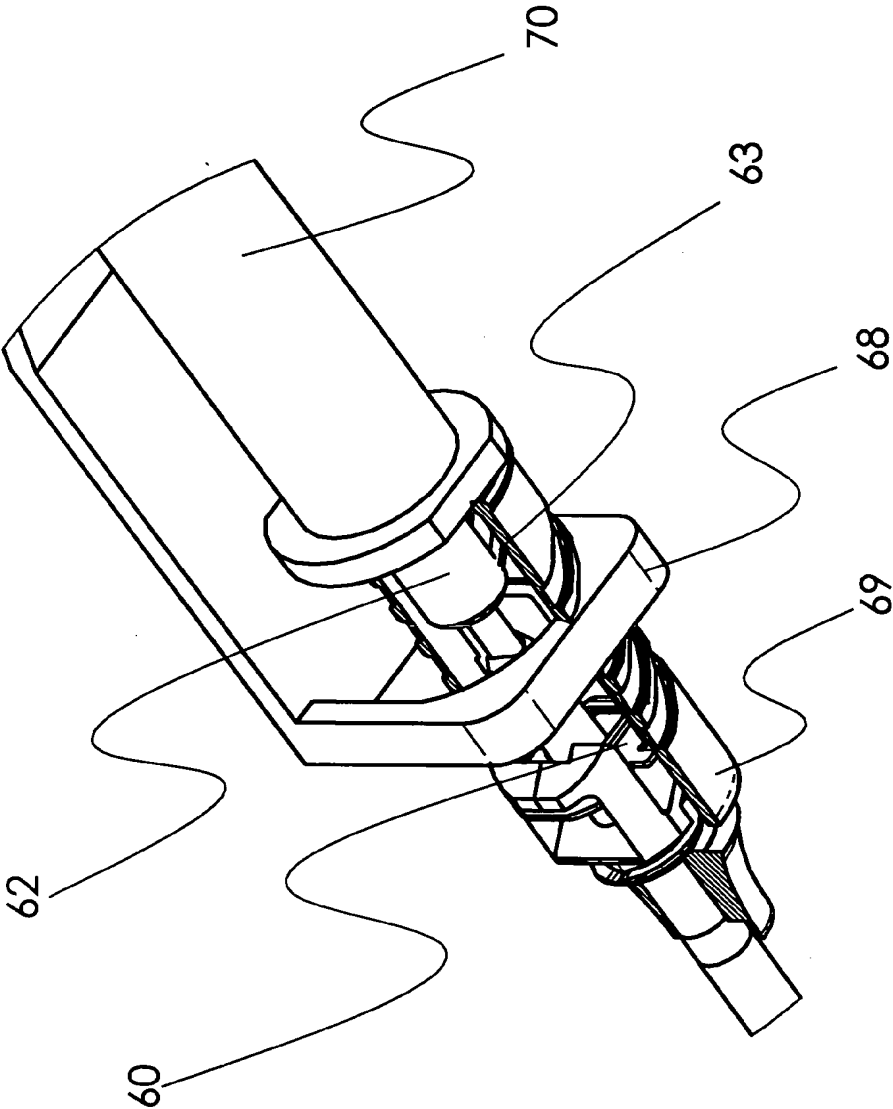


FIGURE 7

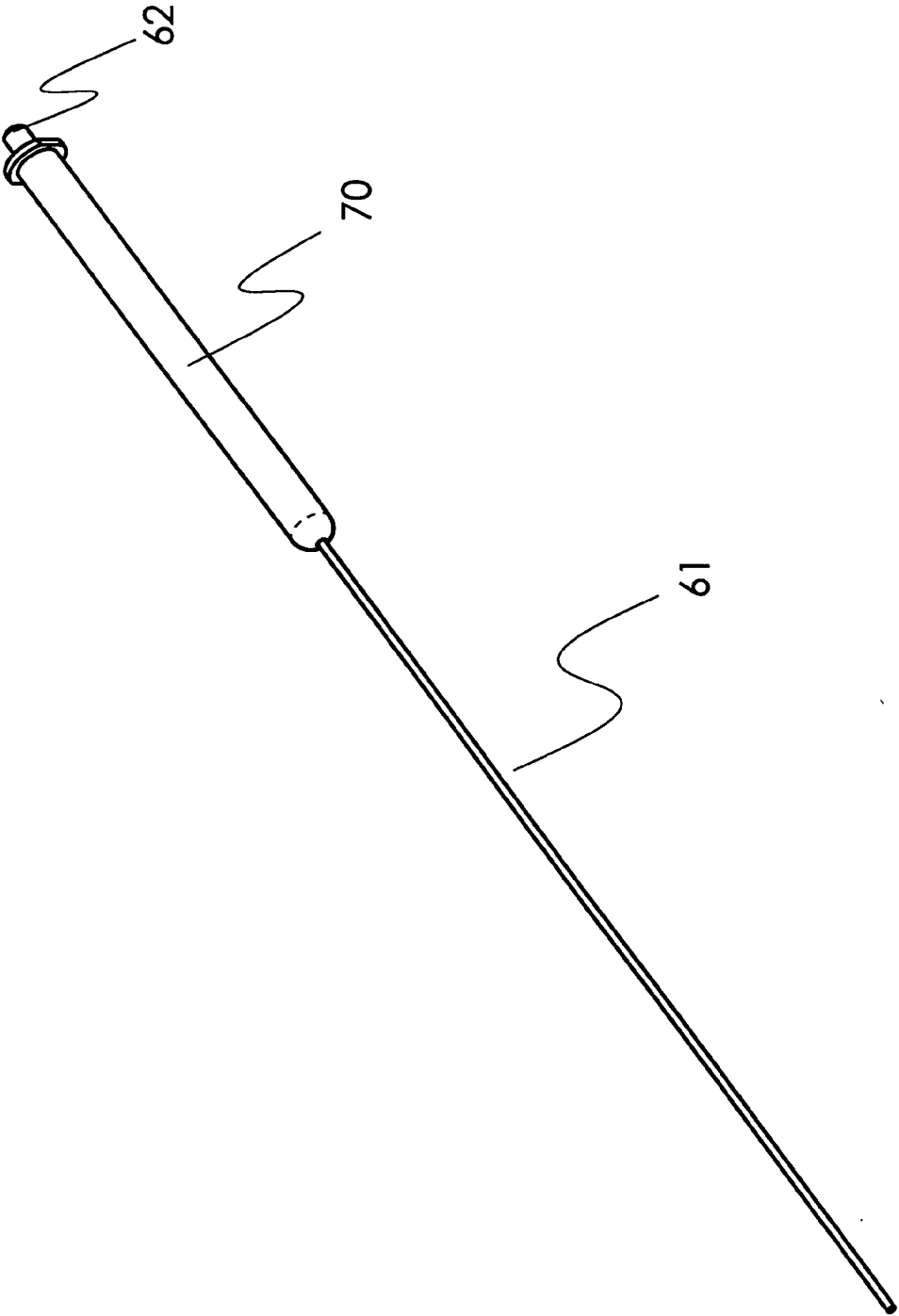


FIGURE 8

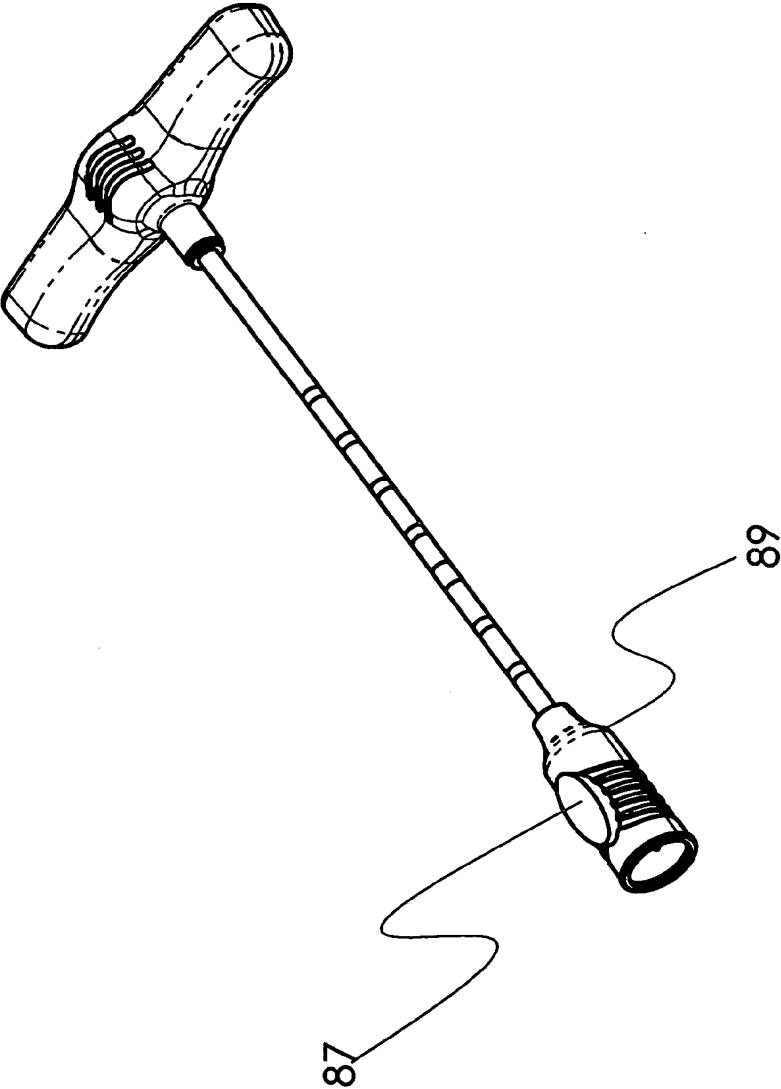


FIGURE 9

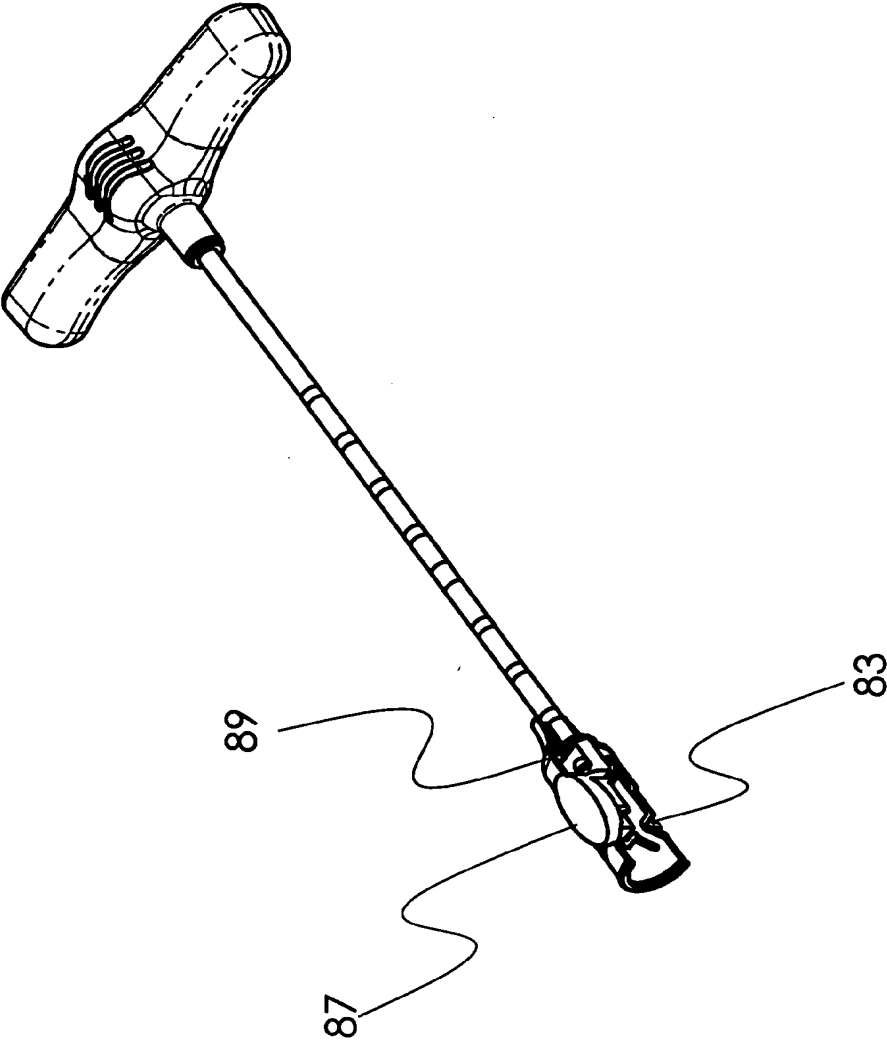


FIGURE 10

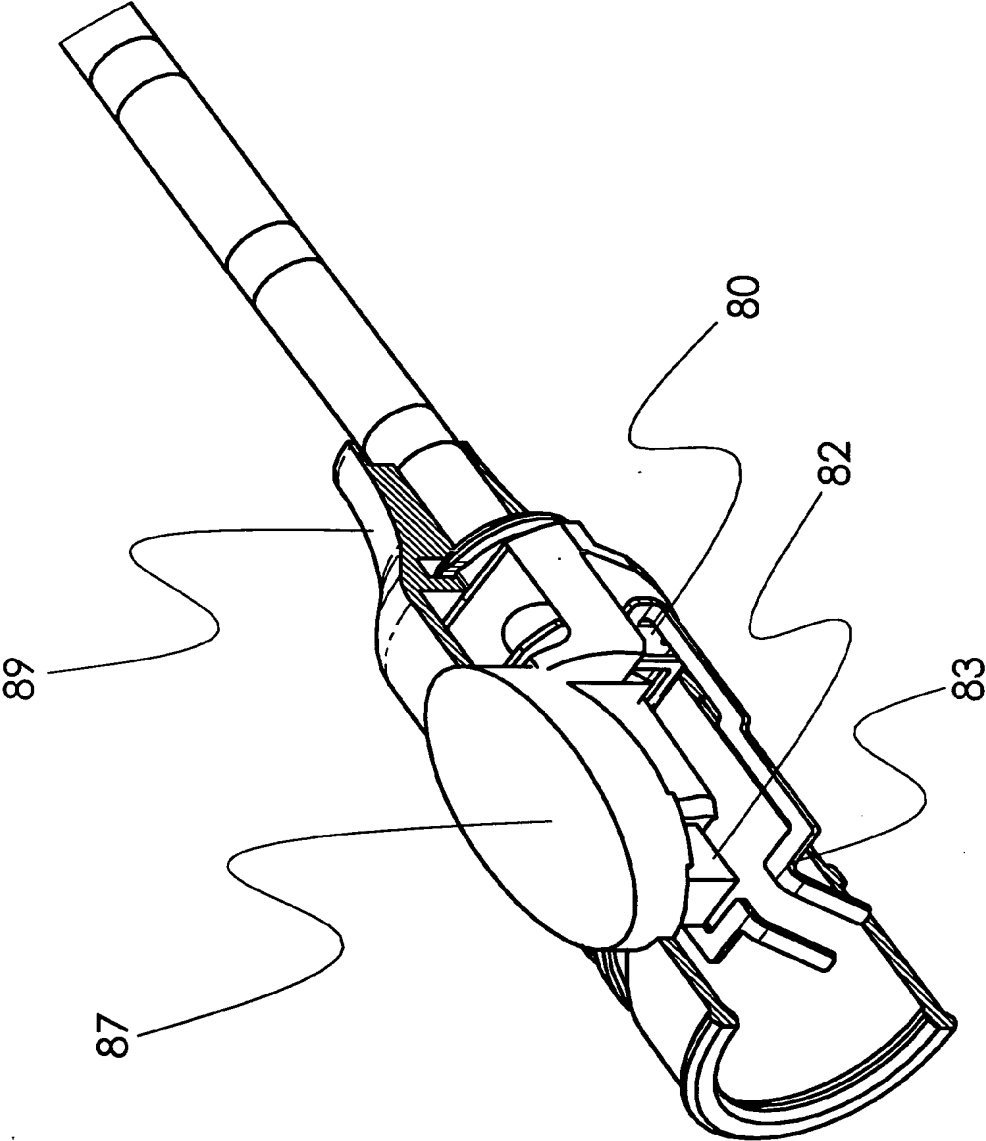


FIGURE 11

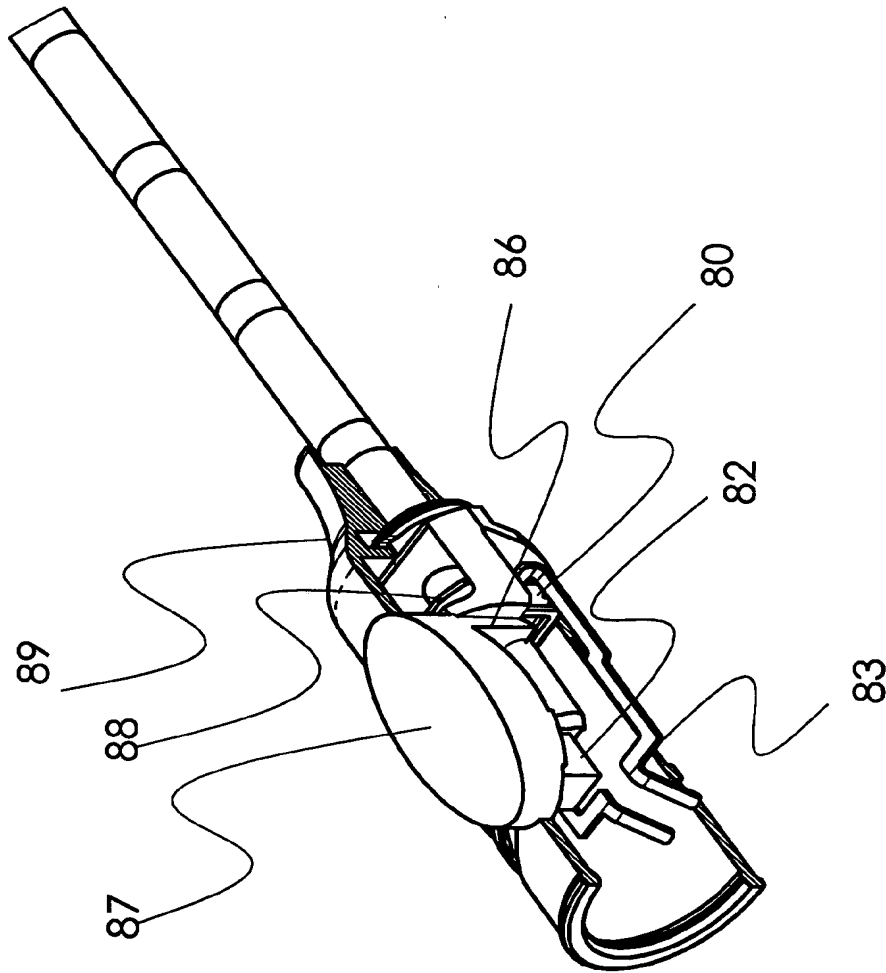


FIGURE 12

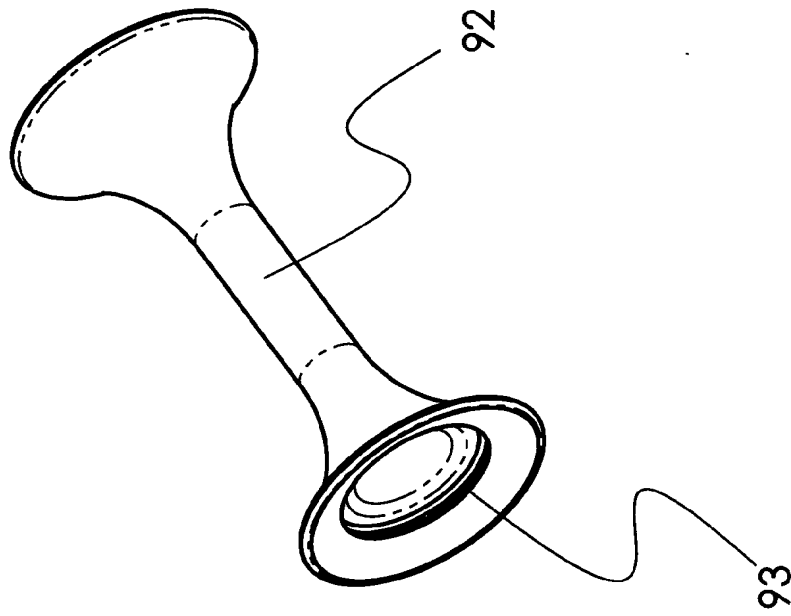


FIGURE 13

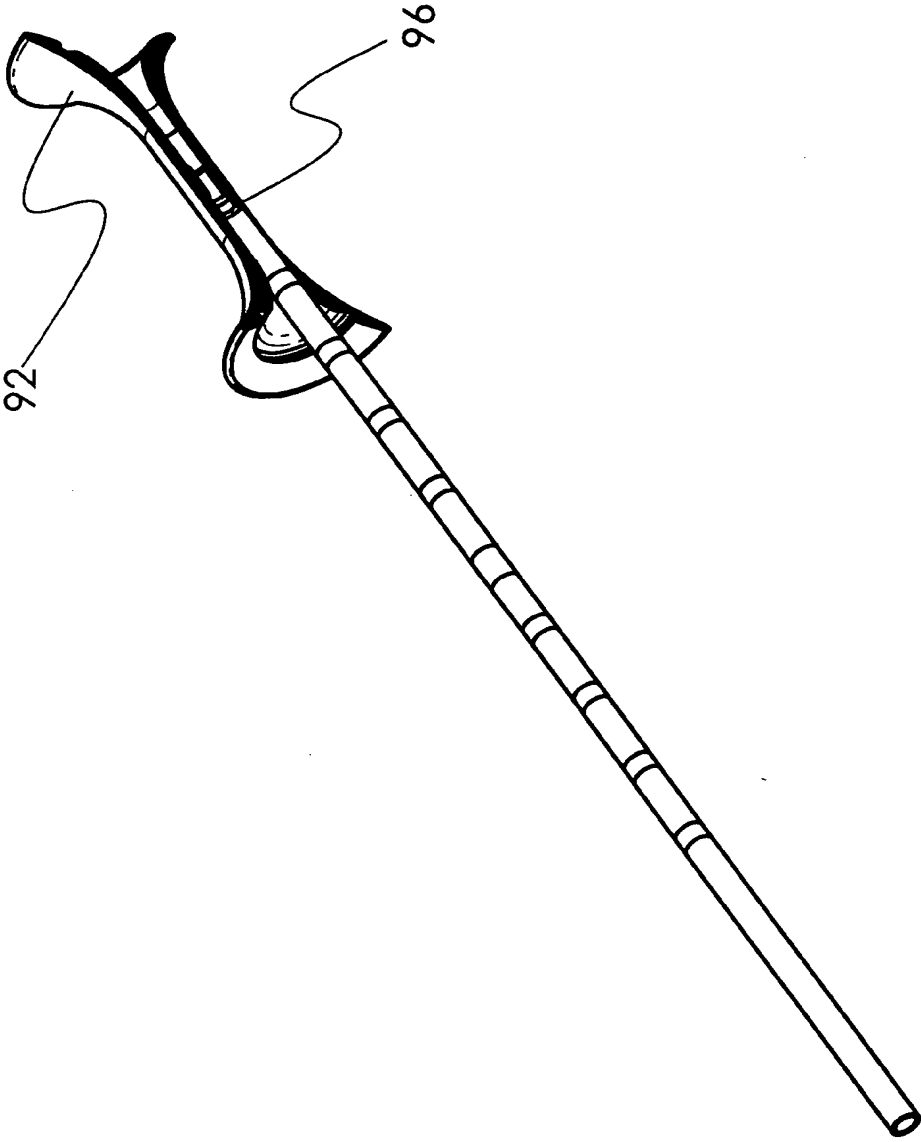


FIGURE 14

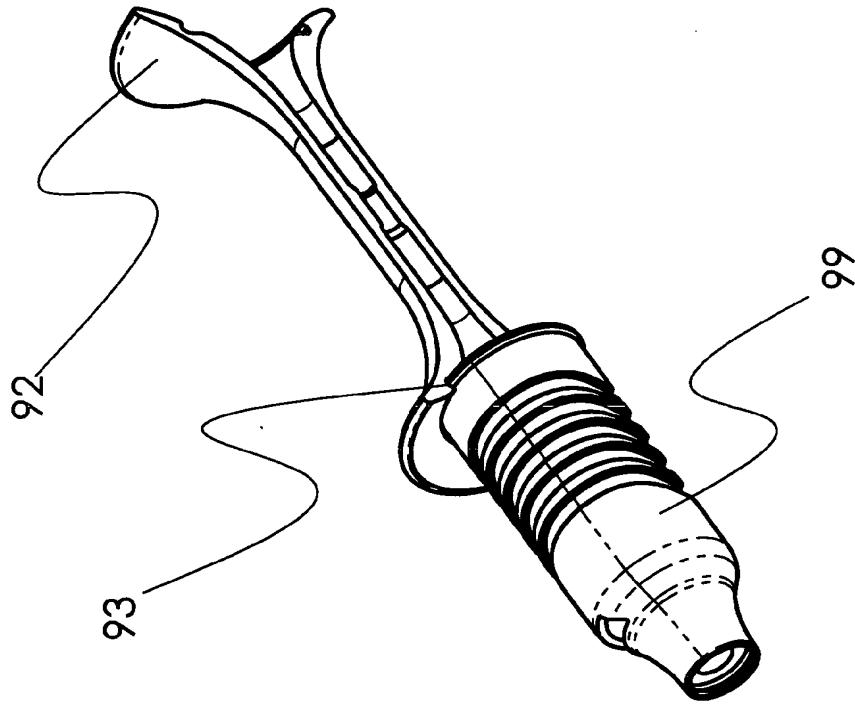


FIGURE 15

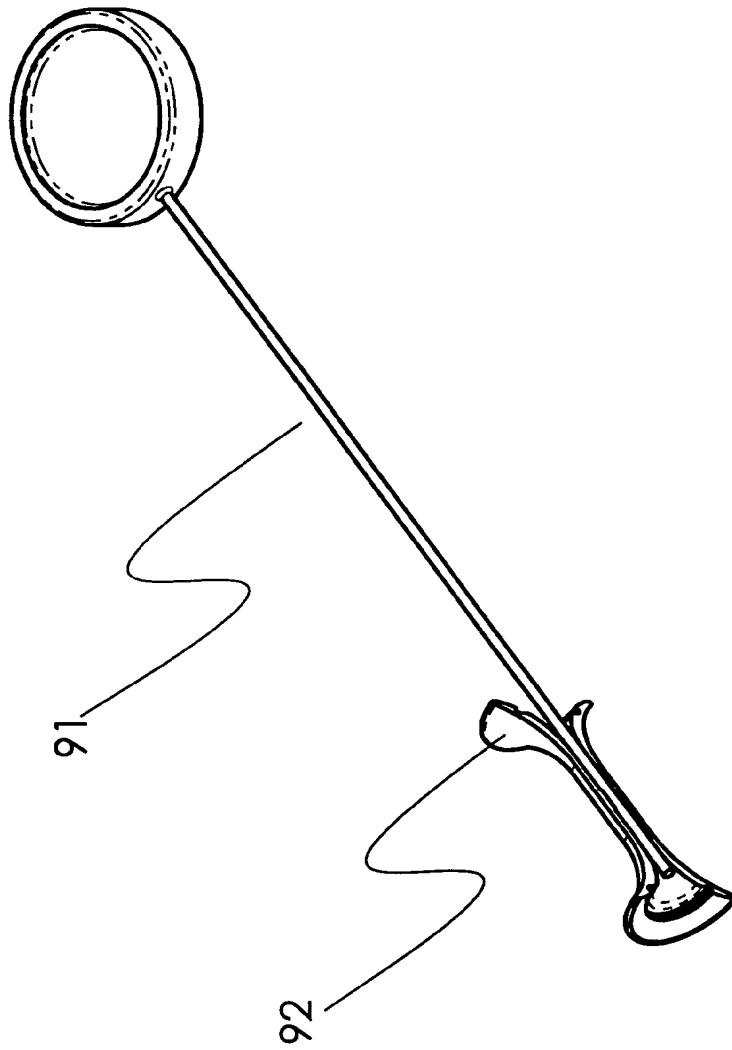


FIGURE 16

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor(s), I hereby declare that:

TYPE OF DECLARATION

This declaration is for a **PROVISIONAL** patent application.

INVENTORSHIP IDENTIFICATION

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if two or more names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

SAFETY SHIELD FOR MEDICAL NEEDLES

SPECIFICATION IDENTIFICATION

The specification

☒ is attached hereto.

☐ was filed on _____ and has U.S. Application Number _____,
and was amended on _____.

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, Section 1.56.

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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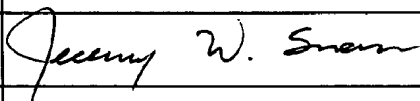
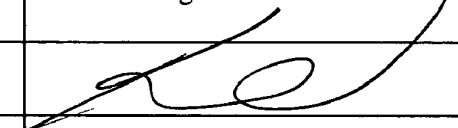
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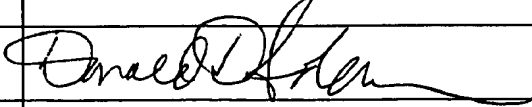
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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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